K002223

Epic Medical Equipment Services, Inc.
1800 10TH STREET, SUITE 300, PLANO, TEXAS 75074

AUG 22 2000

510(k) Summary

Submitter Information:

Epic Medical Equipment Services, Inc.
1800 E. 10th Street, Suite 300
Plano, TX 75074

Contact:

Krista Oakes
Vice President, Regulatory Affairs and Quality Assurance
Telephone: (972) 801-9854
Fax: (972) 801-9859

Date Prepared:

July 14, 2000

Product Name:

Common Name: SpO_2 Sensor (accessory to pulse oximeter)
Classification Name(s): Oximeter (accessory)

Predicate Device:

This product is a modification to the Epic SpO_2 sensor Model # E403-09 marketed under 510(k) # K990082 and is also substantially equivalent to the Hewlett-Packard SpO_2 sensor model M1191A marketed under K923343.

Description:

The SpO_2 Sensor is an electro-optical sensor which functions without skin penetration, electrical contact, or heat transfer. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector.

The LED's and photodiode are contained in a soft PVC finger pad, housed in a hard ABS shell that is placed on the desired patient digit secured by a spring clip. The sensor cable is 12 feet in length and is terminated in a HP 12 pin connector.

Intended Use:

The SpO_2 Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring for patients weighing more than 30 kg.

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Comparison to Predicate Device:

	Predicate Device – Epic SpO_2 Sensor - Model # E403-09 (E412-09) **(ref. # K990082)**	**Predicate Device - Hewlett-Packard SpO_2 Sensor – Model M1191A (ref. # K923343)**	**Proposed Epic SpO_2 Sensor – Model # E412-20**
Intended use	Continuous SpO_2 monitoring	Continuous SpO_2 monitoring	Continuous SpO_2 monitoring
Anatomical sites	Finger/toe	Finger/toe	Finger/toe
Target patient population	> 30kg	> 50kg	> 30kg
Accuracy claim	+/-2 digits @ 65%-100% SpO2 +/- 1 std. deviation	+/-2.5digits @ 70%-100% SpO2 +/- 1 std. deviation	+/-2.5 digits @ 70%-100% SpO2 +/- 1 std. deviation
Patient use/reuse	Multi-patient reusable	Multi-patient reusable	Multi-patient reusable
Sterility	Non-sterile device	Non-sterile device	Non-sterile device
Description of patient attachment	Hard ABS outer shell, spring clip, soft finger pad	Soft silicone boot	Hard ABS outer shell, spring clip, soft finger pad
Cable length	3 - 12 feet	2 feet	12 feet
Accessories	E710-09 adapter cable 10 feet	M1940A adapter cable 10 feet	None
Oximeter compatibility	Datex	Hewlett-Packard (Agilent) oximeters Release E or later	Hewlett-Packard (Agilent) oximeters Release E or later
Connector design	DB-9 connector	HP 12 pin connector	HP 12 pin connector
Material	Cable jacket – Polyurethane blend Finger pad – PVC Clip – ABS	Cable jacket - polyurethane Boot - Silicone	Cable jacket –PVC Finger pad – PVC Clip – ABS
Cable structure	Shielded twisted pair/shielded triad	Shielded twisted pair/shielded triad	Shielded twisted pair/shielded triad
Resistors	33.2K, 16.2K	2.0K	2.0K
LED wavelength	Red 660nm nominal Infrared 900nm nominal	Red 660nm nominal Infrared 880nm nominal	Red 660nm nominal Infrared 880nm nominal
Photodiode Active Area	$8.23mm^2$	$8.0mm^2$	$8.23mm^2$
Protection against ambient light noise	Opaque materials, labeling warnings regarding use under excessive light	Opaque materials, labeling warnings regarding use under excessive light	Opaque materials, labeling warnings regarding use under excessive light
Biocompatibility standards	ISO 10993-1/EN 30993-1	ISO 10993-1/EN 30993-1	ISO 10993-1/EN 30993-1
Safety standards	EN 60601-1 EN 60601-1-2	EN 60601-1 EN 60601-1-2	EN 60601-1 EN 60601-1-2

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	Predicate Device – Epic SpO_2 Sensor Model # E403-09 (ref. # K990082)	**Predicate Device - Hewlett-Packard SpO_2 Sensor – Model M1191A (ref. # K923343)**	**Proposed Epic SpO_2 Sensor – Model # E412-20**
Other standards	EN 865/ASTM F1415-92	EN 865/ASTM F1415-92	EN 865/ASTM F1415-92

Performance Data & Conclusions:

Clinical data has established product performance and accuracy within the original oximeter manufacturer's specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2000

Ms. Krista Oakes
Epic Medical Equipment Services, Inc.
1800 10th Street, Suite 300
Plano, TX 75074

Re: K002223
SpO_2 Finger Sensor - E412-20
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: July 21, 2000
Received: July 24, 2000

Dear Ms. Oakes:

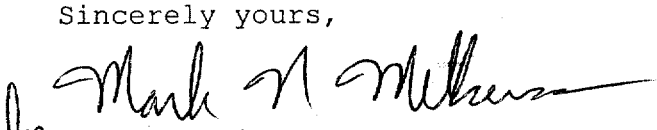
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Epic Medical Equipment Services, Inc.
1800 10TH STREET, SUITE 300, PLANO, TEXAS 75074

Statement of Indications For Use

510(k) # K002223
Device Name: SpO_2 Finger Sensor

Indications for Use:
The SpO_2 Finger Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring for patients weighing more than 30 kg.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

for Mark N Milhern
Division of Cardiovascular & Respiratory Devices
510(k) Number K002223